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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,637	03/24/2004	Jun Feng	SYR-DPPIV-5004-C2	8940
32793	7590	03/01/2006	EXAMINER	
TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			MCKENZIE, THOMAS C	
			ART UNIT	PAPER NUMBER

1624

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,637

Applicant(s)

FENG ET AL.

Examiner

Thomas McKenzie, Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to an application filed on 3/24/04. There are eighty-six claims pending. Claims 1-86 are compound claims. The application concerns some quinazoline compounds.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claim 86 and parts of claims 1-14, 25, 32, 58, 59, 66, 69-71, 74, 84, and 85, drawn to quinazoline compounds of the formula XXVIII with $Q = C=O$, CS , or $C=NR_9$, and $R_3 = R_4 = \text{benzo}$ or of formula XXIX with $Q = C=O$, CS , or $C=NR_9$ and $J = K = L = M = CR_{12}$, classified in class 544, subclass 287, among others.
- II. Claim parts of claims 1-14, 25-32, 58, 59, 66, 69-71, 74, 84, and 85, drawn to 2H-benzo[e][1,2,4]thiadiazine compounds of the formula XXVIII with $Q = SO$ or SO_2 , and $R_3 = R_4 = \text{benzo}$ or of formula XXIX with $Q = SO$ or SO_2 and $J = K = L = M = CR_{12}$, classified in class 544, subclass 12.
- III. Claim parts of claims 1-13, 15, 25-32, 34, 35, 58, 60, 66, 69-71, 75, 85, and 85, drawn to pyrido[3,2-d]pyrimidin-4(3H)-one compounds of the formula XXVIII with $Q = C=O$, CS , or $C=NR_9$, and $R_3 = R_4 =$

pyrido[3,2-d] or of formula XXIX with $Q = C=O$, CS, or $C=NR_9$, $J = N$, and $K = L = M = CR_{12}$, classified in class 544, subclass 279.

- IV. Claim parts of claims 1-13, 16, 25, 30, 31, 34, 35, 58, 60, 66, 69-71, 76, 84, and 85, drawn to pyrido[4,3-d]pyrimidin-4(3H)-one compounds of the formula XXVIII with $Q = C=O$, CS, or $C=NR_9$, and $R_3 = R_4 =$ pyrido[4,3-d] or of formula XXIX with $Q = C=O$, CS, or $C=NR_9$, $K = N$, and $J = L = M = CR_{12}$, classified in class 544, subclass 279.
- V. Claim parts of claims 1-13, 17, 25-29, 33-35, 58, 60, 66, 69-71, 77, 84, and 85, drawn to pyrido[3,4-d]pyrimidin-4(3H)-one compounds of the formula XXVIII with $Q = C=O$, CS, or $C=NR_9$, and $R_3 = R_4 =$ pyrido[3,4-d] or of formula XXIX with $Q = C=O$, CS, or $C=NR_9$, $L = N$, and $J = K = M = CR_{12}$, classified in class 544, subclass 279.
- VI. Claim parts of claims 1-13, 18, 25-35, 58, 60, 66, 69-71, 78, 84, and 85, drawn to pyrido[2,3-d]pyrimidin-4(3H)-one compounds of the formula XXVIII with $Q = C=O$, CS, or $C=NR_9$, and $R_3 = R_4 =$ pyrido[2,3-d] or of formula XXIX with $Q = C=O$, CS, or $C=NR_9$, $M = N$, and $J = K = L = CR_{12}$, classified in class 544, subclass 279.

- VII. Claim parts of claims 1-13, 15, 17, 19, 23, 25-29, 33, 58, 60, 61, 64, 66, 69-71, 75, 77, 79, 82, 84, and 85, drawn to pyrimido[5,4-d]pyrimidin-4(3H)-one compounds of the formula XXVIII with Q = C=O, CS, or C=NR₉, and R₃ = R₄ = [5,4-d]pyrimidine or of formula XXIX with Q = C=O, CS, or C=NR₉, J = L = N, and K = M = CR₁₂, classified in class 544, subclass 256, among others.
- VIII. Claim parts of claims 1-13, 15, 16, 19, 23, 25, 30, 31, 58, 60, 61, 64, 66, 69-71, 75, 76, 79, 82, 84, and 85 drawn to pyrimido[5,4-c]pyridazin-8(7H)-one compounds of the formula XXVIII with Q = C=O, CS, or C=NR₉, and R₃ = R₄ = [5,4-c]pyridazine or of formula XXIX with Q = C=O, CS, or C=NR₉, J = K = N, and L = M = CR₁₂, classified in class 544, subclass 235.
- IX. Claim parts of claims 1-13, 16, 17, 20, 23, 25, 58, 60, 62, 64, 66, 69-71, 75-77, 80, 82, 84, and 85, drawn to pyrimido[4,5-d]pyridazin-4(3H)-one compounds of the formula XXVIII with Q = C=O, CS, or C=NR₉, and R₃ = R₄ = [4,5-d]pyridazine or of formula XXIX with Q = C=O, CS, or C=NR₉, K = L = N, and J = M = CR₁₂, classified in class 544, subclass 236.

- X. Claim parts of claims 1-13, 16, 18, 21, 23, 25, 58, 60, 62, 64, 66, 69-71, 76, 78, 80, 82, 84, and 85, drawn to pyrimido[4,5-d]pyrimidin-4(3H)-one compounds of the formula XXVIII with $Q = C=O$, CS, or $C=NR_9$, and $R_3 = R_4 = [4,5-d]$ pyrimidine or of formula XXIX with $Q = C=O$, CS, or $C=NR_9$, $K = M = N$, and $J = L = CR_{12}$, classified in class 544, subclass 256.
- XI. Claim parts of claims 1-13, 15, 18, 22, 23, 25-32, 58, 60, 63, 64, 66, 69-71, 75, 78, 81, 82, 84, and 85, drawn to pteridine compounds of the formula XXVIII with $Q = C=O$, CS, or $C=NR_9$, and $R_3 = R_4 =$ pyrazine or of formula XXIX with $Q = C=O$, CS, or $C=NR_9$, $J = M = N$, and $K = L = CR_{12}$, classified in class 544, subclass 257.
- XII. Claim parts of claims 1-13, 17, 18, 22, 23, 25-29, 33, 58, 60, 63, 64, 66, 69-71, 77, 78, 81, 82, 84, and 85, drawn to pyrimido[4,5-c]pyridazin-5(6H)-one compounds of the formula XXVIII with $Q = C=O$, CS, or $C=NR_9$, and $R_3 = R_4 = [4,5-c]$ pyridazine or of formula XXIX with $Q = C=O$, CS, or $C=NR_9$, $L = M = N$, and $J = K = CR_{12}$, classified in class 544, subclass 236.
- XIII. Claim parts of claims 1-13, 15-17, 19, 20, 23-25, 58, 60-62, 64-66, 69-71, 75-77, 79, 80, and 82-85, drawn to pyrimido[5,4-

d][1,2,3]triazin-8(7H)-one compounds of the formula XXVIII with Q = C=O, CS, or C=NR₉, and R₃ = R₄ = [5,4-d][1,2,3]triazine or of formula XXIX with Q = C=O, CS, or C=NR₉, J = K = L = N, and M = CR₁₂, classified in class 544, subclass 184, among others.

XIV. Claim parts of claims 1-13, 15, 16, 18-25, 30-32, 58, 60-66, 69-71, 75, 76, and 78-85, drawn to pyrimido[4,5-e][1,2,4]triazin-8(7H)-one compounds of the formula XXVIII with Q = C=O, CS, or C=NR₉, and R₃ = R₄ = [4,5-e][1,2,4]triazine or of formula XXIX with Q = C=O, CS, or C=NR₉, J = K = M = N, and L = CR₁₂, classified in class 544, subclass 184.

XV. Claim parts of claims 1-13, 15, 17-19, 21-29, 33, 58, 60, 61, 63-66, 69-71, 75, 77-79, and 81-85, drawn to pyrimido[5,4-e][1,2,4]triazin-5(6H)-one compounds of the formula XXVIII with Q = C=O, CS, or C=NR₉, and R₃ = R₄ = [5,4-e][1,2,4]triazine or of formula XXIX with Q = C=O, CS, or C=NR₉, J = L = M = N, and K = CR₁₂, classified in class 544, subclass 184.

XVI. Claim parts of claims 1-13, 16-19, 21-25, 58, 60, 62-66, 69-71, 76-78, and 80-85, drawn to pyrimido[4,5-d][1,2,3]triazin-5(6H)-one compounds of the formula XXVIII with Q = C=O, CS, or C=NR₉, and

$R_3 = R_4 = [4,5-d][1,2,3]$ triazine or of formula XXIX with $Q = C=O$, CS, or $C=NR_9$, $K = L = M = N$, and $J = CR_{12}$, classified in class 544, subclass 184.

XVII. Claim parts of claims 1-13, 15-25, 58, 60-66, 69-71, and 75-85, drawn to pyrimido[5,4-e][1,2,3,4]tetrazin-8(7H)-one compounds of the formula XXVIII with $Q = C=O$, CS, or $C=NR_9$, and $R_3 = R_4 = [1,2,3,4]$ tetrazine or of formula XXIX with $Q = C=O$, CS, or $C=NR_9$, and $J = K = L = M = N$, classified in class 544, subclass 179, among others.

XVIII. Claim parts of claims 1-13, 15-35, 58, 60-66, 69-71, and 75-85, drawn to among others 2H-pyrido[2,3-e][1,2,4]thiadiazine compounds of the formula XXVIII with $Q = SO$ or SO_2 , and $R_3 = R_4 =$ six-membered nitrogen-containing or of formula XXIX with $Q = SO$ or SO_2 , and at least one of $J = K = L = M = N$, classified in class 544, subclass 10.

XIX. Claims 36-57, drawn to among others 6,7-dihydro-3H-cyclopenta[d]pyrimidin-4(5H)-one compounds of the formula XXXI with $Q = C=O$, CS, $C=NR_9$, SO, or SO_2 , and $W = X = Y = C, N, O$, or S, classified in class 544, subclass 253, among others.

XX. Claims parts of claims 58-85, drawn to among others pyrimido[4,5-e][1,2,3]oxathiazin-8(7H)-one compounds of the formula XXXVa, XXXVb, or XXXVc with $Q = C=O$, CS, $C=NR_9$, SO, or SO_2 , and at least one of $J = K = L = M = S$, SO, SO_2 , or O, classified in class 544, subclass 2, among others.

3. Should Applicants elect any of group XVIII-XX then further restriction will be required as to the specific heterocyclic core Applicants wish to have examined and an election of species requirement will be made.

4. The inventions are distinct, each from the other because of the following reasons: inventions I-XX are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the heterocyclic core of the structure given in claim 1 is the ring including radicals R_3 and R_4 . This bicyclic ring is a mandatory feature and ranges in size from nine to ten atoms with multiple possible heteroatoms. These multiple claimed rings are chemically non-equivalent and are not art-recognized as sharing the same biological properties. Inventions I-III, VII-IX, XI, XIII, and XVII-XX

have acquired a separate status in the art as shown by their different classification, thus the patent search required for Group I is not co-extensive with that required for Groups II, III, VII-IX, XI, XIII, and XVII-XX. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.


5. Although Groups III-VI, VII & X, IX & XII, and XIII-XVI are classified together these are patentably distinct ring systems, *i.e.* a reference against one ring would not be a reference against another. These will also raise separate issues of enablement for making and enablement for using. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

6. Should Applicants traverse the restriction requirement on the grounds that the different core rings are not patentably distinguishable, Applicants should identify such evidence now of record or submit any such evidence that shows the groups to be obvious variants. Such evidence may be used in a rejection under 35 USC 103(a) if the Examiner finds any of the Groups unpatentable over the prior art.

Conclusion

7. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

8. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 9:00am to 5:30pm, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, SPE of Art Unit 1624, at (571)-272-0661.


Thomas C. McKenzie, Ph.D.
Primary Examiner
Art Unit 1624

TCMcK/me